PSJ10 Exh 5

Distributors, pharmacies and manufacturers respond to previously unreleased DEA data about opioid sales

washingtonpost.com/investigations/distributors-pharmacies-and-manufacturers-respond-to-previously-unreleased-dea-data-about-opioid-sales/2019/07/16/7406d378-a7f6-11e9-86dd-d7f0e60391e9_story.html

Investigations

Add to list

Cardinal Health headquarters in Dublin,Ohio, McKesson Corporation in Robbinsville, New Jersey, AmerisourceBergen in Saint-Laurent, Quebec, Canada, and Mallinckrodt Pharmaceuticals in Hayward, California. (Jay LaPrete/Bloomberg News and Kristoffer Tripplaar/Sipa via AP Images)

By Aaron C. Davis and
Jenn Abelson
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A yearlong legal battle waged by The Washington Post and HD Media, publisher of the Charleston Gazette-Mail in West Virginia, resulted in a ruling Monday releasing government data tracking sales of billions of opioid pills in the U.S. from 2006 to 2012.

The data in the Drug Enforcement Administration's Drug Automation of Reports and Consolidated Orders System, known as ARCOS, reveals what each company knew about the number of pills it was shipping and dispensing and precisely when they were aware of those volumes, year-by-year, town-by-town.

Lawsuits against the drug companies now allege they allowed some of the highly addictive drugs to reach the streets of communities large and small, despite persistent red flags that those pills were being sold in apparent violation of federal law and diverted to the black market.

[Five takeaways from the DEA's pain pill database]

The Post on Tuesday asked opioid distributors, pharmacies and manufacturers to respond to information contained in the database. The paper also asked them to respond to three major allegations made by plaintiffs in ongoing lawsuits:

1. That your company helped fuel the opioid epidemic by manufacturing, distributing or dispensing hundreds of millions of pain pills?

2. That your company along with other companies conspired to flood the nation with opioids?

3. That your company failed to report suspicious orders to the DEA and filled those orders to maximize profits?

The Post also asked for comment from the Healthcare Distribution Alliance, an industry trade group.

These were their public statements to The Post:

DISTRIBUTORS

AmericansourceBergen: "Broadly providing retroactive DEA data to plaintiffs' law firms solely for litigation purposes offers a very misleading picture regarding efforts being made around diversion. This data has never previously been given to anyone outside DEA, and therefore has not been available to inform the order monitoring programs and decision-making of distributors like AmerisourceBergen.

"After providing daily order reports to DEA, distributors such as AmerisourceBergen have at no time been privy to how this information was used by DEA, despite consistently seeking guidance on how to most effectively walk the tightrope of providing access to needed, FDA-approved medications while playing a role – however limited, given lack of interaction with patients – in combating the diversion of these same medications.

"Only recently did DEA share any of this data with distributors or manufacturers, when it was compelled to through the passage of the SUPPORT Act in late 2018 to make limited information from the database available to distributors.

“The fact that our market share of these controlled substances seems to be far smaller than our total market share is a testament to the fact that our controls played an important role in enabling us to, as best we could, walk the tight rope of creating appropriate access to FDA approved medications while combatting prescription drug diversion.”

Cardinal Health: “Cardinal Health is an intermediary in the pharmaceutical supply chain and plays an important but limited and specific role: to provide a secure channel to deliver medications of all kinds from the hundreds of manufacturers that make them to our thousands of hospital and pharmacy customers licensed to dispense them to patients, and to work diligently to spot, stop and report suspicious orders of medications.

“Cardinal Health is proud to operate a constantly adaptive and rigorous system to combat controlled substance diversion. We have learned from our experience and the threats the pharmaceutical supply chain faces, and as a result our anti-diversion program today is stronger and more effective as it continues to evolve. We have increased the size of our anti-diversion team, including bringing in personnel with additional regulatory, pharmaceutical, and law enforcement experience. We have developed an analytical model to evaluate our pharmacy customers, assigned threshold ordering limits to them, created a centralized database to store and track data on customers and orders, and enhanced policies and procedures for anti-diversion personnel. Over the years, we have trained thousands of our people on anti-diversion practices. Our people operate in good faith, our goal is to get it right, and we have stopped suspicious orders for the shipment of hundreds of millions of dosage units of controlled substances over the last decade.

“As we fulfil our role in the closed supply chain, we are in full compliance with all applicable federal and state laws, which include the requirement to report to state and federal regulators those orders deemed suspicious, despite there being only vague guidance from the Drug Enforcement Administration on what constitutes an unusual, or suspicious, order.

“We report those suspicious orders to state boards of pharmacy and to the DEA, but we do not know what these government entities do with those reports, if anything. Distributors have no law enforcement power and, unlike the regulators which oversee and regulate the manufacture, distribution, prescribing and dispensing of controlled substances, cannot stop physicians from writing prescriptions for medication nor take unilateral action to block DEA- and state-licensed pharmacies’ ability to dispense medication.

“Cardinal Health shares the judgment of top policymakers that too many prescriptions have been written for too many opioid pills over the past decade, a trend that began with changes in the medical community’s attitudes toward managing pain. The DEA, the only entity with the ability to limit production of prescription opioids as it sets an annual quota of the amount allowed to be manufactured, also until recently continuously raised these annual production quotas. From 2006 to 2014, the DEA’s authorized quota rose 140%. Thus, the quantity of opioid pills sold is a direct reflection of the number of prescriptions written by healthcare providers and filled by licensed dispensers, neither of which wholesale distributors can influence.

“Cardinal Health cares deeply about the opioid epidemic and takes seriously our commitment, in cooperation with everyone else in the prescription drug supply chain – state and federal government regulators, pharmaceutical manufacturers, doctors and other healthcare providers, insurers and pharmacies – to find and support solutions to this national challenge.

“In addition, Cardinal Health will continue, as we have for over a decade, to make a meaningful difference by raising awareness about the dangers of overprescribing and actively supporting efforts to address it. We also will continue to vigorously defend ourselves in all opioid-related legal matters.”

McKesson Corp.: “As the ARCOS data demonstrates, McKesson has consistently disclosed controlled substance transactions to the DEA. For decades, DEA has had exclusive access to this data, which can identify the total volumes of controlled substances being ordered, pharmacy-by-pharmacy, across the country.

“McKesson distributes prescription opioids and other medications in response to orders placed by state-licensed and DEA-registered pharmacies, and those pharmacies may only dispense these medications to patients with a valid prescription written by a government-licensed health care provider.

“The allegations made by the plaintiffs are just that – allegations. They are unproven, untrue and greatly oversimplify the evolution of this health crisis as well as the roles and responsibilities of the many players in the pharmaceutical supply chain. Any suggestion that McKesson influenced the volume of opioids prescribed or consumed in this country would reflect a misunderstanding of our role as a distributor.”

PHARMACIES

CVS: “The plaintiffs’ allegations about CVS in this matter have no merit and we are aggressively defending against them. The fact is that we are committed to the highest standards of ethics and business practices, including complying with all federal and state laws governing the dispensing of controlled substance prescriptions.

“We are also dedicated to helping reduce prescription drug abuse and diversion. We have stringent policies, procedures and tools to help ensure that our pharmacists properly exercise their professional responsibility to evaluate controlled substance prescriptions before filling them.

“Over the past several years, we have taken numerous actions to strengthen our existing safeguards to help address the nation’s opioid epidemic. This includes millions of hours training our pharmacy teams about responsibilities and best practices regarding controlled substances.

“When reviewing information in the ARCOS database about CVS, it is important to keep the following in mind for context:

“We did not, and still do not, distribute Schedule II controlled substances such as oxycodone and fentanyl. We only distribute Schedule III-V controlled substances to our retail pharmacies.

“CVS Pharmacy is one of the two largest retail pharmacies in the nation. During the covered time period of 2006-2012, CVS had an average market share of over 18% for all retail prescriptions dispensed in the country. During those last two years, our market share for all retail prescriptions dispensed nationally was 20-21%.

“We dispensed over 4.2 billion retail prescriptions during that time period and opioid medications were a very small percentage of that total.

“Pharmacies dispense medication, including controlled substances, to patients who have authorized prescriptions written by doctors, physicians and other prescribers.”

Walgreens: “Walgreens pharmacists are highly trained professionals committed to dispensing legitimate prescriptions that meet the needs of our patients. Walgreens has not distributed prescription controlled substances since 2014 and before that time only distributed to our chain of pharmacies. Walgreens has been an industry leader in combatting this crisis in the communities where our pharmacists live and work.”

Walmart: Declined to comment.

MANUFACTURERS

Actavis Pharma: “Teva acquired Actavis in 2016 and cannot speak to any systems in place beforehand. I can also not confirm any of your statistics without more specificity on medicines, locations and additional detail.

“That said, overall, generic medicines automatically replace branded medicines at the pharmacy with absolutely no influence from Teva. Teva has not conspired, failed to report suspicious orders or contributed to the abuse of opioids in the U.S. in any way. We maintain a comprehensive and robust system to prevent suspicious orders from ever entering the market.”

Endo Pharmaceuticals: “Regarding the lawsuit, it is Endo’s policy not to comment on current litigation. Our comments regarding the topic of opioids can be found on our website. In the letter, Endo states:

“Since its founding as a family business in 1920, Endo has evolved into a generics and specialty branded pharmaceutical company whose products help millions of patients lead healthier lives. We are deeply concerned about the opioid abuse crisis, a public health challenge unprecedented in scope, severity and complexity. We believe this crisis can only be solved through intensive collaboration among the multiple stakeholders involved in our healthcare system.

“The U.S. Food and Drug Administration (FDA) has worked to balance access to pain care medications for appropriate patients while aggressively mitigating the risks of opioid abuse. Endo supports these efforts and has taken parallel actions. Since our new Executive Leadership Team began working together in September 2016, Endo voluntarily stopped promoting opioid products to healthcare professionals and eliminated the Company’s entire pain product salesforce. Endo also voluntarily withdrew Opana® ER from the market, discontinued the research and development of new opioid products and implemented additional anti-diversion measures, including product serialization aimed at thwarting counterfeiting and theft to protect patient safety.

“While we are proud of Endo’s actions, neither we nor any other single actor can solve the opioid abuse crisis. Instead, any solution must be multifaceted and consider not only the product supply chain, but also individual risk factors and other factors affecting utilization decisions, together with scientific, legislative and regulatory measures, training, treatment and education. Criminal trafficking of opioids (including heroin and fentanyl), illegal Internet sales and importation must also be addressed. Finally, the legitimate access needs of the millions of patients suffering from acute or chronic pain who rely on opioid medications must be considered. We remain committed to working collaboratively and proactively on a comprehensive solution to the opioid abuse crisis and to continuing Endo’s longstanding mission of improving patients’ lives.”

Mallinckrodt: “The Drug Enforcement Administration determines the total quantity of Schedule II opioids needed each year to meet legitimate medical, scientific and research needs in the U.S. Our DEA registrant company, SpecGx LLC, cannot and does not produce more opioids than the annual limit set for the company by the DEA. SpecGx sells only to DEA-approved distributors and other entities, who are themselves registered with and monitored by the DEA. In addition, through its ARCOS database, DEA monitors the flow of these DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level.

“Mallinckrodt has for years been at the forefront of preventing prescription drug diversion and abuse, and has invested millions of dollars in a multi-pronged program to address opioid abuse. Those efforts include the purchase and donation of nearly two million drug disposal pouches, and working with policymakers, community leaders, law enforcement and industry partners to ensure the responsible use of pain medication and preventing unused medications from ending up in the wrong hands. The company will continue to support these efforts. For more information on Mallinckrodt’s work to combat prescription drug abuse and misuse, please visit www.mallinckrodt.com/solutions [mallinckrodt.com].”

Purdue Pharma: “We have no further comment on the release of the ARCOS data beyond what was stated in our brief.

“Purdue Pharma vigorously denies the claims brought forth in the MDL, which are based on mischaracterizations and allegations we believe are without merit. We are confident in the strength of our legal arguments, and will continue to defend ourselves in the litigation.”

TRADE GROUP:

Healthcare Distribution Alliance: “The ARCOS data show that distributors have consistently reported sales of opioid-based medications, along with the quantity of the order and the identity of the receiving pharmacy to the DEA. Distributors only recently received access to the full set of data with information about the total shipment of opioid medicines a particular pharmacy received from all distributors. The DEA has been the only entity to have all of this data at their fingertips and it could have used the information to consistently monitor the supply of opioids and when appropriate, proactively identify bad actors. Unlike the DEA, distributors have no authority to stop physicians from writing prescriptions, nor can they take unilateral action to halt pharmacies’ ability to dispense medication.”

Read more:

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